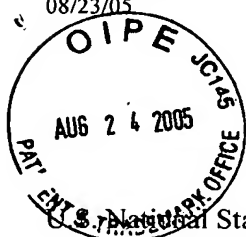


1006 Rec'd PCT/PTO 24 AUG 2005

IN THE UNITED STATES RECEIVING OFFICE (RO/US)  
Designated/Elected Office (DO/EO/US)



U.S. National Stage of

International Application No.: PCT/GB2003/004050

International Filing Date: 22 September 2003

Earliest Priority Date: 20 September 2002

Applicants: Malcolm Carter, Elisa Henderson, Richard Kelsey, Lara Wilson, Phil Chambers,  
Debra Taylor and Stan Tyms

Title: BENZODIAZEPINE DERIVATIVES AND PHARMACEUTICAL  
COMPOSITIONS CONTAINING THEM

Attorney's Docket No.: 3890.1000-000

Date:

8-24-05

EXPRESS MAIL LABEL NO. EV215897094US

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:  
☐ a Statement under 37 CFR 1.97(e), as checked below, and  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application  
filewrapper.  
(Filed after payment of issue fee)

101 528250

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references, B1-B21 and C1-C2, are enclosed.
    - ☒ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
  - ☒ The "concise explanation" requirement (non-English references) for reference(s) B9 and C1, under 37 CFR 1.98(a)(3) is satisfied by:
    - ☐ the explanation provided on the attached sheet.
    - ☐ the explanation provided in the Specification.
    - ☐ submission of the enclosed International Search Report.
    - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
  - ☒ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

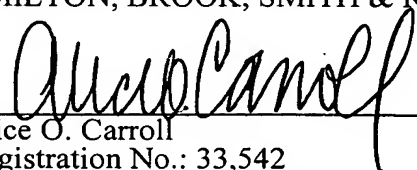
Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By

  
\_\_\_\_\_  
Alice O. Carroll  
Registration No.: 33,542  
Telephone: (978) 341-0036  
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated:

*August 24, 2005*

|  |  |                  |                               |  |
|--|--|------------------|-------------------------------|--|
| PTO-1449 REPRODUCED<br><br><b>SUPPLEMENTAL INFORMATION DISCLOSURE<br/>STATEMENT<br/>IN AN APPLICATION</b><br><br><b>August 23, 2005</b><br><br>(Use several sheets if necessary) | ATTORNEY DOCKET NO.<br>3890.1000-000   |                  | APPLICATION NO.<br>10/528,250 |  |
|  | FIRST NAMED INVENTOR<br>Malcolm Carter |                  | FILING DATE<br>June 21, 2005  |  |
|  | EXAMINER                               | CONFIRMATION NO. | GROUP                         |  |

## U.S. PATENT DOCUMENTS

| EXAM-<br>INER<br>INI-<br>TIAL | REF.<br>NO. | DOCUMENT NUMBER<br>Number-Kind Code (if known) | ISSUE DATE /<br>PUBLICATION DATE<br>MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT<br>OF CITED DOCUMENT |
|-------------------------------|-------------|--|--|--|
|                               | A1          | 5,776,930                                      | 07-07-1998                                     | Lynch, Jr., <i>et al.</i>                          |
|                               | A2          | 6,436,971 B2                                   | 08-20-2002                                     | DeMarsh, <i>et al.</i>                             |
|                               | A1          | 5,593,988                                      | 01-14-1997                                     | Tahara, <i>et al.</i>                              |
|                               | A4          | 5,218,114                                      | 06-08-1993                                     | Bock, <i>et al.</i>                                |
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|                               | A11         |  |  |  |
|                               | A13         |  |  |  |
|                               | A16         |  |  |  |
|                               | A15         |  |  |  |
|                               | A16         |  |  |  |
|                               | A19         |  |  |  |
|                               | A18         |  |  |  |
|                               | A19         |  |  |  |
|                               | A20         |  |  |  |
|                               | A21         |  |  |  |
|                               | A20         |  |  |  |
|                               | A23         |  |  |  |
|                               | A23         |  |  |  |
|                               | A25         |  |  |  |

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|  | FIRST NAMED INVENTOR<br>Malcolm Carter |                  | FILING DATE<br>June 21, 2005  |  |
|  | EXAMINER                               | CONFIRMATION NO. | GROUP                         |  |

## FOREIGN PATENT DOCUMENTS

|  |     | DOCUMENT NUMBER<br>Country Code-Number-Kind Code<br>(if known) | DATE<br>MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT<br>OF CITED DOCUMENT  | TRANSLATION<br>YES NO |  |
|--|-----|--|--------------------|---|-----------------------|--|
|  | B1  | EP 0 167 919 A2  | 01-15-1986         | Merck & Co., Inc.                                   |                       |  |
|  | B2  | EP 0 434 364 A2  | 06-26-1991         | Merck & Co., Inc.                                   |                       |  |
|  | B1  | EP 0 475 231 A1  | 03-18-1992         | F. Hoffmann-La Roche AG                             |                       |  |
|  | B1  | EP 0 508 797 A1  | 10-14-1992         | Merck & Co., Inc.                                   |                       |  |
|  | B5  | EP 0 508 797 A1  | 10-14-1992         | Merck & Co., Inc.                                   |                       |  |
|  | B6  | EP 0 523 845 A2  | 01-20-1993         | Merck & Co., Inc.                                   |                       |  |
|  | B9  | WO 98/18473  | 05-07-1998         | Merck & Co., Inc.                                   |                       |  |
|  | B8  | CN1338456  | 03-06-2002         | Ins. of Medical Materials Chin<br>(CN)              | (abstract<br>only)    |  |
|  | B9  | WO 00/28947  | 05-25-2000         | Sanofi-Synthelabo                                   | abstract              |  |
|  | B10 | WO 99/19306  | 04-22-1999         | Board of Regents, The University<br>of Texas System |                       |  |
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|  | B15 | WO 93/07129  | 04-15-1993         | Yoshitomi Pharmaceutical<br>Industries, Ltd.        | (abstract<br>only)    |  |
|  | B16 | EP 0 421 802 A2  | 04-10-1991         | Merck & Co., Inc.                                   |                       |  |
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|  | B18 | WO 00/66106  | 11-09-2000         | The Regents of the University of<br>Michigan        |                       |  |
|  | B19 | JP 02-215774   | 08-28-1990         | Roussel Uclaf                                       | abstract              |  |
|  | B20 | EP 0 638 560 A1  | 02-15-1995         | Yoshitomi Pharmaceutical<br>Industries, Ltd.        |                       |  |
|  | B21 | WO 02/40023 A1   | 05-23-2002         | SmithKline Beecham Corporation                      |                       |  |

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|  | FIRST NAMED INVENTOR<br><b>Malcolm Carter</b> |                  | FILING DATE<br><b>June 21, 2005</b>  |  |
|  | EXAMINER                                      | CONFIRMATION NO. | GROUP                                |  |

| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) |   |  |
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| C1   | Del Giudice, <i>et al.</i> , Chemical Abstract 97:23755 CA, "Synthesis of 2- and 3-amino-1, 4-benzodiazepines," <i>Farmaco, Edizione Scientifica</i> 37(5):434-452 (1982).        |  |
| C2   | Kelsey, R., et al., "Synthesis, Resolution and Evaluation of Small Molecule Inhibitors of Respiratory Syncytial Virus," Presented at 44 <sup>th</sup> ICAAC, Oct. 30-Nov 2, 2004. |  |
| C3   |   |  |
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